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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,422	10/07/2005	Vinod Chintamani Malshe	044.P001	6676

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EXAMINER	
HELM, CARALYNNE E	

ART UNIT	PAPER NUMBER
1615	

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10/01/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/552,422	MALSHE ET AL.	
	Examiner	Art Unit	
	CARALYNNE HELM	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 June 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-8 and 10-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 6-8, and 10-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 14, 2010 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The four factual inquires of Graham v. John Deere Co. have been fully considered and analyzed in the rejections that follow.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3, 6, 11, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Penhasi (previously cited)

Penhasi teaches catheters, surgical mesh and films structures for their devices composed of a blend of elastomeric and non-elastomeric polymers along with a drug (see paragraphs 16, 22-24, 53, 58, and claim 10; instant claims 1, 6, 11, 19). "'[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.' In re

Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)....The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., In re Garnero, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979)" (see MPEP 2113). Therefore when no structure is implied, the product-by-process recitation does not add any limitations that affect patentability. Claims 1, 6, and 19 recite a product-by-process in their recitation of molded implants. The process of molding confers no additional structural limitations to the implant. Therefore any component that is capable of being implanted is interpreted to meet this limitation. The catheters, surgical mesh and films are all capable of being implanted; therefore they meet the limitations of molded or melt molded non-stent implants. In addition, Penhasi teaches drug being incorporated in a polymer matrix where, polyethylene sebacate is taught as one of the envisioned non-elastomeric polymers (paragraph 35 line 33-34; instant claims 1 and 2). Anti-restenotic drugs are envisioned in the polymer blend and are well known to include anti-inflammatories, anti-proliferatives, anti-coagulants, as well as anti-platelets (see paragraph 46; instant claim 3).

Although Penhasi does not provide an explicit example where polyethylene sebacate is the non-elastomeric polymer in the blend, it would have been obvious to one of ordinary skill in the art at the time of the invention to follow the explicit teachings of Penhasi to select polyethylene sebacate as the non-elastomeric polymer for the

drug/polymer blend and form it into a film, catheter or mesh as taught to yield a device with good mechanical integrity that will have the ability to retain its shape in expanded mode as taught (see claim 10). Therefore claims 1, 3, 6, 11, and 19 are obvious over Penhasi

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Penhasi as applied to claims 1, 3, 6, 11, and 19 above, and further in view of Zhu et al. (previously cited).

Penhasi makes obvious the invention of claim 1 where a pharmaceutical composition composed of polyethylene sebacate and a pharmaceutically active agent is shaped as a non-stent implant or film. Penhasi does not explicitly teach the molecular weight of the polyethylene sebacate.

Zhu et al. teach that aliphatic polyesters are preferred among biodegradable polymers due to their better biodegradability properties and that this property depends upon their molecular weight (see paragraph 1 lines 5-8; instant claim 2). In addition, Zhu et al. also teach molecular weights that range from approximately 800 to approximately 20400 for degradable aliphatic polyesters (see tables 1 and 2).

Since polyethylene sebacate is an aliphatic polyester, it would have been obvious to select one with a molecular weight between 800 and 20,400, as taught by Zhu et al., because it was a known finite range of molecular weight preparations available at the time of the invention which would have had a reasonable expectation of success in the invention of Penhasi (obvious to try). Since 20,400 is explicitly recited

and falls within the molecular weight range of instant claim 2, this combination of teachings renders obvious the limitations of this claim. Therefore claim 2 is obvious over Penhasi in view of Zhu et al.

Claims 1, 3-4, 8, 10, 12, 15, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burns et al. (previously cited).

The instant disclosure does not distinguish between the structure of nanoparticles, microparticles, and microcapsules, therefore they are interpreted to be the same absent additional limitations in the claim that distinguish them.

Burns et al. teach microspheres composed of polymers that are envisioned for biomedical applications (see abstract). The particles are sized from 0.5 microns to 20 microns, can be interpreted as microparticles, nanoparticles, and microcapsules, and are envisioned for sustained (controlled) release (see paragraphs 18 and 32; instant claims 12 and 15). Particles of this size would be capable of being injected and can be administered parenterally, transdermally, orally, and nasally (mucosal) (see paragraph 94; instant claims 8 and 17). Polyethylene sebacate is taught as a polymer contemplated in the particles (see paragraph 34; instant claims 1). Burns et al. go on to teach that bioactive agents included in the particles are present at 0.5% to 65% (see paragraph 39; instant claim 4). Particular bioactive agents contemplated include steroids, analgesics, anti-histamines (anti-allergic agents), and anti-cancer agents (see paragraph 89; instant claim 3). Additionally, Burns et al. teach that the particles can be incorporated within a gel (see paragraph 93; instant claim 10). Although the instant

intended use is not explicitly envisioned, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The gel suspended microparticles of Burns et al. would be capable of being administered to a periodontal space and thereby meet the limitations of the recited intended use. While Burns et al. do not provide an example where polyethylene sebacate is the polymer in their microspheres, it would have been obvious to one of ordinary skill in the art at the time of the invention to follow their teachings and select this polymer for their bioactive containing microspheres because it is explicitly envisioned in this role by Burns et al. and would have had a reasonable expectation of success for biomedical applications as they envisioned. Therefore claims 1, 3-4, 8, 10, 12, 15, and 17 are obvious over Burns et al.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Burns et al. as applied to claims 1, 3-4, 8, 10, 12, 15, and 17 above, and further in view of Yoshioka et al. (previously cited) and Hoshino et al. (previously cited).

Burns et al. make obvious nanoparticles composed of the linear aliphatic polyester, polyethylene sebacate, and a drug that are envisioned for controlled release of the drug (see instant claim 1). Burns et al. do not explicitly teach the presence of a lipase in the nanoparticles.

Yoshioka et al. teach the inclusion of an agent in a polymeric drug delivery system to hydrolyze the polymer and allow control of the degradation rate of the polymer and subsequent rate of drug release (see page 341 column 1-page 342 column 1 line 9 and page 346 column 2 paragraph 2).

Hoshino et al. teach that lipases were known to degrade a linear aliphatic polyester of the same form as the polyethylene sebacate taught by Burns et al. (e.g. polybutylene succinate).

Since Burns et al. sought to provide controlled release from their nanoparticles (microspheres) and the incorporation of a degradation inducing agent in polymeric drug delivery systems was known to aid in controlling the release of drug, it would have been obvious to one of ordinary skill in the art at the time of the invention to include such a compound in the nanoparticles of Burns et al. Given that Hoshino et al. teach lipases as a degradation inducing agent for linear aliphatic polyesters of the same form as polyethylene sebacate, it would also have been obvious for this artisan to select a lipase to include in the microparticles of Burns et al. and this addition would have had a reasonable expectation of success. Therefore claim 16 is obvious over Burns et al. in view of Yoshioka et al. and Hoshino et al.

Claims 1, 3-4, 8, 12-14, 17, and 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thompson et al. (US Patent No. 5,635,216) in view of Farachi et al. (previously cited)

The instant disclosure does not distinguish between the structure of nanoparticles, microparticles, and microcapsules, therefore they are interpreted to be the same absent additional limitations in the claim that distinguish them.

Thompson et al. teach a microparticle (microcapsules) preparation where a peptide bioactive is dispersed within a polyester matrix that is suitable for injection (see column 2 lines 21-26 and 37-38; instant claims 1, 3, 8, and 17). The bioactive agent is present at 5 to 25% in the polymer (see column 2 lines 23-25; instant claim 4). Thompson et al. teach the microparticles as having sustained (prolonged) release properties (see column 12 lines 62-65; instant claim 12). The polyester can be any polyester that biodegrades (see column 3 lines 59-61). Thompson et al. go on to teach the presence of a stabilizer in the preparation, where poly(vinyl alcohol) is explicitly exemplified (see column 5 lines 30-36; instant claims 13-14 and 20-21). The particles are prepared by dispersing the polyester, solubilized in an organic solvent, into an aqueous solution of poly(vinyl alcohol) and peptide (see example 1). The resulting oil-in-water emulsion is agitated and vacuum filtered to collect the particles (see example 1). "'[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.' In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)....The structure implied by the process steps should be considered when assessing the patentability of

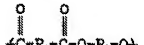
product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., In re Garnero, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979)" (see MPEP 2113). Therefore when no structure is implied, the product-by-process recitation does not add any limitations that affect patentability. Instant claims 13-14 and 20-21 recite a product-by-process that structurally requires a polymer core with drug coated that is coated with a stabilizer, where polyethylene sebacate is located anywhere in the structure. While the claims are not limited to the method recited, Thompson et al. explicitly teach the limitations of the method and the microparticles it generates with the exception of polyethylene sebacate as the polyester.

Farachi et al. teach that the polyalkylene sebacates of their invention are particularly good for their biodegradability (see column 2 lines 41-47 and 63-65). Farachi et al. also exemplify polyethylene sebacate as a particular polyalkylene sebacate (see column 4 lines 57-59; instant claims 1 and 20).

As a polyester that was touted for its biodegradability, it would have been obvious to one of ordinary skill in the art at the time of the invention to select polyethylene sebacate as taught by Farachi et al. for the polyester in the invention of Thompson et al. as the simple substitution of one known element for another with a predictable outcome. Therefore claims 1, 3-4, 8, 12-14, 17, and 20-21 are obvious over Thompson et al. in view of Farachi et al.

Claims 1 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duan et al. (previously cited) in view of Nakamura et al. (US Patent No. 4,524,191) and Burns et al.

Duan et al. teach a composition composed of particulate (granule) drug, a dispersing agent that is a compound comprising a chain of diol/diacid condensate and a propellant (see page 3 lines 1-8; instant claim 1). The dispersant compound is taught to have the form



where R_1 and R_2 are organic moieties arising from the diacid and diol, respectively (see page 3 lines 13-22). The chain of diol/diacid condensate is taught to be made from any straight chain dicarboxylic acid and dihydric alcohol, where polyethylene glycol is envisioned as such an alcohol (see page 4 lines 7-8, 22, and 28; instant claim 1). Duan et al. go on to teach that the micronized particulate drug can be coated with the dispersant (see page 14 lines 24-29). Duan et al. do not explicitly teach sebacic acid as the diacid (e.g. polyethylene sebacate as the dispersing aid).

Nakamura et al. teach polyethylene sebacate as a dispersing aid (see column 7 line 41 and column 8 lines 1 and 5; instant claim 1).

Burns et al. teach microspheres composed of polymers that are envisioned for biomedical applications (see abstract). Polyethylene sebacate is taught as a polymer contemplated in the particles (see paragraph 34; instant claims 1). In addition, Burns et al. to teach that bioactive agents included in the particles (see paragraph 39).

Since polyethylene sebacate was already known at the time of the invention to serve as a dispersing agent and to be safe for biomedical application and Duan et al. teach diol/diacid condensates prepared from any straight chain diacid and dihydric polyethylene glycol, it would have been obvious to one of ordinary skill in the art at the time of the invention to select polyethylene sebacate as the diol/diacid condensate coating the particulate drug of Duan et al. as the simple substitution of one know element for another with a predictable outcome. "'[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.' In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)....The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., In re Garnero, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979)" (see MPEP 2113). Therefore when no structure is implied, the product-by-process recitation does not add any limitations that affect patentability. Instant claim 7 recites a product-by-process whose structural limitations require, at most, a coating of polyethylene sebacate on the surface of a drug containing granule. A granule is interpreted as a particle, thus the teaching of

Duan et al. in view of Nakamura et al. and Burns et al. renders obvious a particular preparation of drug that is coated with polyethylene sebacate. Moreover whether applied as a coating on the particles directly or solubilized in a propellant, as taught, the dispersant forms a coating on the surface of the drug particles in the preparation taught by Duan et al. (see page 14 lines 12-29). Thus claims 1 and 7 are obvious over Duan et al. in view of Nakamura et al. and Burns et al.

Response to Arguments

Applicant's arguments filed June 16, 2010 have been considered.

In light of the amendment to the claims, the objection and the rejections made under 35 USC 112, second paragraph.

Rejection under 35 USC 103(a) over Penhasi in vie of Farachi et al. Zhu et al. and Jadhav et al.:

In light of the amendment to the claims, this rejection has been altered. However applicants' arguments that the teachings of Penhasi are outside the invention are not accurate. Penhasi explicitly teaches non-stent devices within their invention. Thus in spite of the amendment to the claims, Penhasi is still prior art that is relevant to the invention. Applicants also argue that Penhasi necessarily fails to meet the limitations of an implant made by melt molding. Such a recitation is a product-by-process and is not limited by the process unless the process infers some structural difference or limitation. Melt molding results in a shaped article and such a structure can be obtained by other

methods, thus this recitation does not distinguish its implant over any other implant. While Farachi et al. is not longer cited in this rejection, applicants' argument that polyethylene sebacate is not shown are also inaccurate. While the descriptor polyethylene sebacate is not attached to the polymer of example 4, this compound is the result of the exemplified reaction. Note that example 1 exemplifies the reaction of butandiol with sebacic acid and a catalyst that yield polybutylene sebacate. Similarly in example 4, 1,2-ethandiol is reacted with sebacic acid and the same catalyst. The result of the reaction is therefore polyethylene sebacate.

Rejection under 35 USC 103(a) over Burns et al.:

Applicants argue that the deletion of microparticles from instant claim 1 renders Burns et al. no longer applicable as relevant prior art. Applicants do not provide any structural description of microparticles that distinguishes them from microcapsules. The instant claims even include recitations that describe microparticles as a part of microcapsules (see instant claims 13 and 20). Therefore the recitation "microcapsules" is not distinguished from the recitation "microcapsules" in the absence additional structural limitations. In addition, the size range of the particles taught by Burns also includes nanoparticles which are recited in the instant claims. Therefore the teachings of Burns et al. still meet the limitations of the form of the claimed pharmaceutical composition.

Applicants' arguments concerning the embodiments of Burns et al. that teach the particle structures that result from oil-in-water preparation methods are persuasive,

therefore new grounds of rejection are presented that address the limitations of claims 13-14 and new claims 20-21.

Rejection under 35 USC 103(a) over Burns et a. in view of Yoshika et al. and Hoshino et al.:

Applicants reiterate arguments concerning the pharmaceutical forms taught by Burns et al. which were unpersuasive and were addressed above. Applicants go on to argue against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). While applicants suggest that the teachings of Hoshino et al. directed to the degradation of the polyester poly(lactic acid) by lipase are not applicable to the polyethylene sebacate instantly claimed, Hoshino et al. also teach that the lipases can degrade polybutylene succinate which is the same type of polyester as the polyethylene sebacate. In addition, applicants offer no evidence of unpredictability or any indication that one of ordinary skill in the art would not have expected the lipase to also degrade polyethylene sebacate.

Rejection under 35 USC 103(a) over Duan et al. in view of Farachi et al.:

Applicants argue that Duan et al. do not teach a solid drug delivery system in their teaching of an aerosol. The aerosol taught is solid drug particles with a dispersant. Whether suspended in gas or collected in a container, the particles are still solid and the

drug delivery system of Duan et al. meets the instant limitation of a liquid or solid drug delivery system as required. Applicants reiterate previous arguments about the teachings of Farachi et al. which were addressed above. This rejection has been modified to cite Nakamura et al. and Burns et al. instead of Farachi et al. to provide a more direct motivation to utilize polyethylene sebacate as the dispersant in Duan et al.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is (571)270-3506. The examiner can normally be reached on Monday through Friday 9-5 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on 571-272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Caralynne Helm/
Examiner, Art Unit 1615

/Juliet C Switzer/
Primary Examiner, Art Unit 1634